

June 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln., Room 1061
Rockville, MD 20852

5112 '99 JUN 25 A9:42

Re: Docket No. 99D-0557

To Whom It May Concern:

In response to a Food and Drug Administration (FDA) "industry guidance" notice published in the Federal Register on "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts":

I am strongly opposed to transplanting animal organs, cells, and tissue into humans. They are costly and hazardous to human health.

While the FDA has implemented a ban on the transplantation of vital organs, cells, and tissues from nonhuman primates to humans due to "significant infectious disease risk," the agency has either failed to admit or recognize the dangers posed by transplants from other species. Pigs, having become the species of choice among the various companies vying for a piece of the animal organ market, pose an equally significant risk to human health. Pigs carry a number of known as well as unknown viruses that could "jump" from one species to another as a result of xenografts. Pigs can also harbor swine influenza, Australian paramyxovirus; a novel strain of Hepatitis E, Japanese Encephalitis (JE), and the "Nipah" virus which has infected over 250 humans, killed 100, and led to the slaughter of millions of pigs in Malaysia. These dangers have led the British Government to place a moratorium on all xenografts.

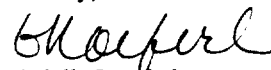
The human immune system is designed to identify and reject foreign objects. Human-to-human transplants have relied on immunosuppressive drugs to control rejection of transplanted organs. Genetic differences make transplants from other species particularly noticeable to the human immune system. Xenograft researchers have developed increasingly powerful immunosuppressive therapies to try to overcome this natural reaction. Without exception these treatments create an immune deficiency that leaves the already ill recipient vulnerable to fatal infections.

Xenografts divert precious resources away from truly life-saving efforts to prevent and treat disease. Each xenograft procedure costs between \$250,000 and \$300,000 to perform. The University of Pittsburgh's experimental transplant program receives more than \$8 million each year in funding, largely through federal grants from the National Institutes of Health. Meanwhile, many promising new treatments for AIDS and other life-threatening diseases go unexplored because of a lack of funding. Ironically, national human organ procurement programs receive less than half a million dollars annually.

An April 1998 General Accounting Office report on organ donation revealed an untapped donor pool of 150,000 people annually which leads many to believe that our government is not, as it claims, doing all it can to increase organ donation. In contrast, countries like Spain, Austria, and Belgium have much higher donation rates than the U.S. due in part to the fact that European organ donor policies assume that every person is an organ donor unless otherwise specified. The burden rests with individuals (or their families) if they do not wish to donate their organs. Even within our current system, patients have a better chance of long-term survival by waiting for a last-minute human organ than by choosing a xenograft.

Why are we wasting time, money and lives when human donations would solve many of these problems? We need to focus on the intelligent, humane solution.

Sincerely,

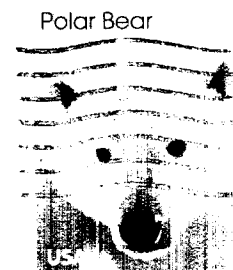

Gabrielle Koefel
W168 N11342 Stone Way #3
Germantown, WI 53022-5825
USA

99D-0557

C 91



Gabrielle Koefel
W168 N11342 Stone Way #3
Germantown WI 53022



Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-0557

20857/0001

